Overview

Why Bar Codes?
Bar codes save lives. In a recent study, 20% of the prescribed medications taken by, or administered to, patients were of the wrong dosage. An estimated seven thousand deaths every year are attributed to medication dispensing errors. Nearly 90% of these could have been prevented by the use of bar codes on unit doses at the time of administration.

The FDA has recognized the demonstrated benefits of bar codes and is expected to mandate bar codes on all over-the-counter and prescription medications in hospitals, including unit doses.

While there is no cure for illegible handwriting on handwritten prescriptions, bar codes can eliminate human error in dispensing and verifying medications. A simple scan of the bar code can confirm the correct medication and dosage. When used with bedside scanning of patient wristbands, unit dose bar codes can also help make sure that the right patient is getting the right medication in the right dosage at the right time.

Bar codes can also help keep health care costs down by providing a quick and accurate way to track and control pharmaceutical inventories.

It all begins with the bar code. And the bar code begins with the platemaking process.

The Reduced Space Symbology (RSS) bar codes used on unit doses have been designed specifically for use in limited spaces. They have been rigorously tested to ensure accuracy and printability.

Total Bar Code Quality
With so much depending on the printed bar code on unit doses, quality is a critical issue. An out-of-spec bar code may be an unreadable bar code. And a bar code with improperly formatted data may be worse than no bar code at all!

Yet many companies invest significant amounts of money in implementing bar code labeling – and do it wrong.

Print quality comes last on this list because, if any of the other five items are not in complete compliance with healthcare guidelines, print quality means nothing.

Total bar code quality begins when an order is placed with a platemaker. The platemaker must first ensure that the requested bar code and supplied data conform to the appropriate rules. Before proceeding, the platemaker must first perform the appropriate:

- encodation check,
- format check, and
- symbology check.

Once these are completed, bar width adjustment must be calculated. Each ink and substrate combination produces different results. In some cases, ink bleeds into the substrate; in other cases, it beads on the surface of the substrate. These differences may be minor or significant.

The platemaker must understand these differences and must produce an image that compensates for this growth or shrinkage in printing. The platemaker should provide test targets to be run on a specific press using a specific anolox roller, ink and substrate combination. Printed test images can then be used to calibrate the image creation and platemaking process.

The bar code imaging system must be calibrated each day and for each new batch of material. Only when the system calibration is completed should the platemaker proceed.

The platemaker must ensure that the bar code image in every step of the process will result in a plate that will produce a high quality printed bar code.

Why Do You Need It?
Printing bar codes is very different from printing human-readable text. Small variations in ink coverage do not significantly affect human-readable text but they can make a bar code unreadable. Most pharmaceutical packaging lines are quite skilled in producing good quality human-readable text. Very few are experts in producing good quality bar codes.

Unreadable bar codes waste healthcare workers’ time and, in certain critical care situations, may hinder the efforts of health care professionals. Even a perfectly printed symbol may be of no use to the health care provider if it has the wrong data or format. At worst, an incorrect bar code may corrupt the medication database and patient record.

With lives at stake, there is no substitute for total bar code quality.
How Do You Get It?
Total bar code quality begins with you, with your information systems, purchasing, printing and packaging/graphics departments.

Information systems must be able to provide correct product identification to the platemaker for each medication and each level of medication packaging.
Purchasing must recognize the need to use a knowledgeable platemaker, not the lowest bidder. 
Printing operations must work with the platemaker to determine the print parameters for every press, ink, substrate, and bar code. The proper ink and substrate must then be used for every run.

Packaging/graphics must inform the purchasing department or platemaker if there are any planned changes in press, ink or substrate. There must also be a single, knowledgeable contact person within your company who can answer any question about the order that the platemaker may have.
The platemaker’s responsibilities are no less demanding.
The platemaker should operate under cGMP guidelines. This is your assurance that the platemaker’s processes and procedures comply with the highest standards.
The platemaker should have process control and documentation procedures in place for every step of the operation from order entry to delivery.

Data and bar code image should be validated and verified at every step and proof of this validation should be provided with the finished plate.

Common Problems
There are four errors that are the most common in generating bar codes:
• wrong data/format encoded
• incorrect check digit
• incorrect bar width adjustment
• incorrect bar/space dimension.
The first two problems occur when customer-supplied data does not conform with guidelines. Data and format checks by the platemaker must identify these errors.
The last two problems result from improper compensation for the output device or for the expected bar growth or shrinkage during printing. Quality assurance before and during image creation and platemaking, and verification of the symbol, must be in place to prevent this.

Recommendations

What Should You Require?
The following quality checks are recommended in order to ensure complete process and production quality control. 

Image Setter & Film Compensation
Each morning, and with each new lot of film, perform a bar width compensation test to determine bar width compensation factor.

Bar Code Generation Verification
• Generate bar code EPS to customer specifications
• Create order packing list for proof reading
• Validate encodation of primary and secondary code (data format/structure)
• Validate bar code parameters:
  - type of bar code (symbology)
  - check digit(s)
  - X dimension
  - height
  - bar width adjustment

Film Master Verification
• Comply with ISO 15421 Bar Code Film Master Specification
• Generate one quality check bar code symbol per customer output with plate film
• Verify bar code quality with verifier specifically designed for film masters
  - bar width adjustment
  - bar/space dimensions

Plate Film Verification
• Make contact proof from plate negative
• Verify to ISO 15416 Bar Code Film Master Specification
• Generate one quality check bar code symbol per customer output with plate film
• Verify bar code quality with verifier specifically designed for film masters
  - bar width adjustment
  - bar/space dimensions

Press Proof Verification
• Pull press proof from plate
• Verify press proof to ISO 15416
  - encodation of primary and secondary code
  - print quality verified: ANSI grade A (adjusted)
• verify each bar code of Master Drug File
• verify two bar codes from all other blisters

Final Plate Quality Assurance
All documentation is checked and verified for accuracy:
• Bar Code Packing List
• Encodation & ANSI Grade
• film master verification print out
• contact proof verification print out
• press proof verification print out

A Summary Sheet of these Recommended Quality Checks is included in this folder. Printing engineers are encouraged to include this Quality Checklist in all their RFQs and platemaker contracts. If the insert is missing, a PDF version can be downloaded from the Quint web site or will be faxed upon request.

www.quintco.com
Phone: 215-533-1988
Fax: 215-533-7784

Proof of Validation
Along with the plate, you should require:
• Plate Press Proof
• Verification Report of Press Proof
Print Quality
Bar codes are governed by a set of rules called a symbology specification. Although the FDA has not yet issued its mandate for bar codes on unit dose medications, it is anticipated that the coding and marking standards issued by EAN.UCC will be adopted. EAN.UCC is the most widely accepted system in healthcare. EAN.UCC is a global set of standards. It has been endorsed as one of only two systems recognized by the Universal Product Number (UPN) initiative within the U.S. Department of Defense for all healthcare products. The EAN.UCC system includes a family of advanced Reduced Space Symbology (RSS) bar code formats specifically designed for unit dose marking and other applications where space is extremely limited. Reduced Space Symbology Limited (RSS Limited) will be used on unit dose medication to encode primary product identification. This is a "conventional" linear bar code. RSS Stacked also encodes primary product identification but is a more complex symbol. The data is "stacked" in two pieces on top of each other. It is used when the RSS Limited symbol is too wide. RSS/Composite is even more advanced. It will encode both primary and secondary product information such as lot/batch and expiration date. RSS/Composite combines a multi-row bar code symbol above an RSS Limited or RSS Stacked symbol.

EAN.UCC Standards
EAN.UCC specifications are available from:
Uniform Code Council
7887 Washington Village Dr.
Ste. 300
Dayton, OH 45459
Tel: 800-543-8137 / 937-435-3870
Fax: 937-435-7317
www.uc-council.org
EAN.UCC specifications cover:
• data content, structure, and format,
• symbology choice (bar code),
• check digit calculation, and
• print quality.

Bar Code Considerations
Bar codes on unit doses are not the same as the typical UPC symbol you see on all consumer goods. Special symbologies have been developed for space constrained applications such as unit doses.

Quality Standards
Bar code image quality is defined by two different ISO standards, one for the film master and one for the printed image.
Film Master Quality
ISO 15421 Bar Code Film Master Specification
Print Quality
ISO 15416 Print Quality Specification
ISO standards are available from:
The International Organization for Standardization (ISO)
www.iso.org

Equipment Specifications
Image generation software must:
• prevent improper X dimensions
• calculate check character(s)
• accurately generate bar width adjustment
Film master verifier:
• must be designed specifically for film masters
• the Asian Film Master verifier is the only verifier designed to comply with ISO 15421 for film masters
Printed symbol verifier:
• must perform 10 equally-spaced verification passes
• must calculate ISO 15416 parameters
• the Webscan TrueCheck is the only verifier designed to verify stacked bar codes

Quint Company equipment and processes conform to all these requirements.